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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,759	05/25/2001	Phyllis Shapiro	708-4057	4368

7590 01/15/2003

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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,759	SHAPIRO, PHYLLIS	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' election with traverse of Specie A (recombinant human hemoglobin) in Paper No. 5, filed 10/25/02, is acknowledged.

Applicants' traversal on the grounds that the restriction to one species of hemoglobin unduly limits the applicants' broadly applicable method is found unpersuasive. The Examiner maintains that examining all species would be an undue search burden as they are distinct entities featuring different critical limitations, as stated in the previous office action.

The requirements are still deemed proper and are therefore made FINAL.

Claims 1-23 are herein under examination.

Claim Objections

Claim 9 is objected to because of the following informality: it is missing a closed parenthesis on line 30. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "blood, plasma, or sample containing a heme-colored interfering substance" on lines 3-4, which is vague and indefinite. It is unclear whether the

"heme-colored interfering substance" is applicable only to the sample or also to the blood and/or plasma. For example, as written, it is reasonable to assume that the "blood" is referring to whole blood. Clarification of the metes and bounds of this claim, via clearer claim wording, is required.

Claims 7, 10, and 17 are rejected because they contain embodiments which are beyond the elected invention. Correction is suggested by stating only the embodiments which are part of the invention. Claims 11 and 18 are also rejected due to their dependency from claims 10 and 17, respectively.

Claim 9 is rejected because the system is meant to "alert" a practitioner of a "need" (line 1) to correct MCH and MCHC, but confusingly there are no practitioner alerting limitations in parts a) or b) of the claim nor any need noted in claim 9, parts a) or b), to correspond to the "need" in line 1 of claim 9. In fact, the system in part b) seems to automatically correct MCH and MCHC, so it is unclear what need or alerting is actually performed by the system. The labeling in part a) may be an alerting of a need, but then it is unclear why one would perform the automatic correcting without a system element directed to practitioner need altering. Claims 10-14 are also rejected due to their dependency from claim 9.

Claim 14 is vague and indefinite because it contains corrections which lack any specification of uncorrected or correct units. It is unclear what unit corrections correspond to 10 or 100. Clarification of this issue via clearer claim wording is required.

Claim 16, lines 24-25, recites the phrase "recovers the original blood chemistry result" which is vague and indefinite, because it is unclear what is meant by this phrase. It may be implied that such a result is the blood chemistry value which would have been measured

"without" interference cited in lines 3-4 of claim 16, but this is only implied and not clearly worded in the claim. Such implied claim interpretations are not deemed to be explicit and thus lack clarity. Claims 9 and 15 are also rejected for containing the same unclarity issue. Claims 10-14 and 17-23 are also rejected due to their direct or indirect dependency from claims 9, 15, and 16.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Chupp et al. (P/N 5,631,165). Chupp et al. teach an automated method for correcting mean cell hemoglobin (MCH) and mean cell hemoglobin concentration (MCHC) in blood by performing the mathematical computations described in (a) – (d) of claim 1 (col. 53, lines 66-67 and col. 54, lines 1-26) and Example 2 (col. 61, lines 38-54). Chupp et al. teach MCH is equal to hemoglobin concentration (HGB) divided by red blood cell concentration (col. 61, lines 45-46) as stated in step a) of claim 1, and then multiplied by a unit conversion factor (col. 61, lines 45-46) as stated in step b) of claim 1. Chupp et al. teach MCHC is equal to HGB divided by hematocrit (HCT) as stated in step c) of claim 1, and then multiplied by a unit conversion factor as stated in step d) of claim 1. Thus, Chupp et al. teach all of the limitations of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chupp et al. (P/N 5,631,165) in view of Chang et al. (P/N 5,200,323).

Chupp et al. teach a system where information about the blood sample is entered into the controller of an automated system which activates the analyzers to perform analyses under the direction of the controller (col. 10, lines 54-67). Chupp et al. describe the system as including an analyzer module, a data station module, and a pneumatic unit (col. 11, lines 27-29). The data station module has "sufficient software algorithms to manipulate measured data, calculate parameters and display results in a variety of formats" (col. 11, lines 62-67). Chupp et al. further discuss the analyzer module in which sample tubes of blood are automatically transported with

bar code labels that can be read with a bar code reader so that sample information can be inputted into the system controller (col. 25, lines 22-35). Chupp et al. teach correcting MCH and MCHC in blood by performing the mathematical computations described in b(1) – (2) of claim 9 where the constants to correct dimension units for formula 1 is 10 and for formula 2 is 100 (col. 53, lines 66-67 and col. 54, lines 1-26). Chupp et al. teach the use of setting hemoglobin flags if any results are abnormal or suspect (col. 61, lines 50-51) which suggests the blood sample tested may be normal or abnormal as stated in claim 3. Chupp et al. also disclose anemic patients with increased reticulocyte counts as indicating rapid erythroid turnover suggesting acute blood loss or hemolysis (col. 1, lines 62-65) as stated in claims 5 and 6. However, Chupp et al. do not teach the presence of an extracellular hemoglobin product or oxygen-carrying blood substitute such as recombinant human hemoglobin.

Chang et al. disclose the use of modified hemoglobin blood substitutes as alternatives to human donor blood, such as recombinant human hemoglobin (col. 3, lines 61-63).

Chupp et al. disclose the presence of classes and subclasses of red blood cells (col. 3, lines 53-54) and how the two methods used can distinguish cells and subdivide the cell types into finer classifications (col. 3, lines 7-14). Chupp et al. also discuss the need for increasing the precision and accuracy of previous manual methods of hematology analysis by using automated systems (col. 7, lines 11-16). Chang et al. point out it would be highly desirable to screen human blood and plasma to determine the safety of modified hemoglobin blood substitutes for humans (col. 4, lines 11-30). A skilled artisan in the art would have been motivated to enhance the automated hematology analyzer and method for correcting MCH and MCHC values in blood, as stated by Chupp et al., by including all types of blood samples in use at the time of the invention

such as those containing modified hemoglobin blood substitutes, as stated by Chang et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use samples including recombinant human hemoglobin and other modified hemoglobin blood substitutes (as stated by Chang et al.) in automated methods and systems of obtaining accurate MCH and MCHC values (as stated by Chupp et al.), because this information would enhance understanding of safety and potential problems of the various types of blood and blood substitutes in humans at the time of the invention, as stated by Chang et al. (col. 4, lines 11-30). Thus, Chupp et al., in view of Chang et al., motivate the instant invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 3, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER